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510(k) SUMMARY

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Date	June 13, 2013
Trade Name	SpineVision LUMIS™ Cannulated Polyaxial Pedicle Screw Fixation System SpineVision U.L.I.S.™ Polyaxial Pedicle Screw Fixation System
Common Name Classification Name	Pedicle Screw Spinal System
Product code	MNI, MNH, KWQ, KWP
CFR section	888.3070
Legally marketed predicate device	SpineVision LUMIS™ Cannulated Polyaxial Pedicle Screw Fixation System and SpineVision U.L.I.S.™ Polyaxial Pedicle Screw Fixation System - K112607 manufactured by SPINEVISION S.A.
SPECIAL 510k	Modification to K112607 (Extension of range of products)

Description

The SpineVision® Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) instrumentations are composed of cannulated (LUMIS™) and non-cannulated (U.L.I.S.™) pedicle screws and fixation rods (SpineVision UNI-Thread™ rods or LUMIS™ percutaneous rods). Their components can be rigidly assembled in a variety of constructs, each corresponding to the needs and anatomy of a specific patient and are supplied non-sterile.

These constructs are assembled using specific instruments. The components of the U.L.I.S.™ and LUMIS™ systems are made of Titanium Ti-6Al-4V ELI complying with ASTM F136 (ISO 5832-3).

The components added within this submission include:

- New reference of LUMIS™ rods (Straight and pre-bent)
- 12 new instruments for LUMIS™ system (MS1-A214 Enlarged screw extender, MS1-A274 Rod Introducer, MS1-A275 Reversed rod introducer, MS1-A276 Rotating rod introducer,

MS1-A235 T10 screwdriver for rod introducer, MS1-A331 Compressor-Distractor, MS1-A332 Extender plug for distractor-compressor, MS1-A333 Screw fixation for distractor-compressor, MS1-A334 Fulcrum connector for distractor-compressor, MS1-A335 Multiple connector for distractor-compressor, MS1-A112 Expander 2, MS1-A113: Expander 3)
- 4 new instruments for U.L.I.S.™ system (IS1-A312 Rocker, IS1-A222 Sleeve for screwdriver, IS1-A225 Sleeve for U.L.I.S.TM screw Ø5,5 mm, IS1-A226 Sleeve for U.L.I.S.TM screw Ø6,5 mm – Ø7,5 mm).

Intended use

When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:

- Degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Fracture
- Spinal stenosis
- Tumors
- failed previous fusion (pseudoarthrosis)

The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the U.L.I.S.™ and LUMIS™ systems are pedicle screw systems intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T10-S1):

- Degenerative spondylolisthesis with objective evidence of neurologic impairment
- Fracture
- Spinal tumor
- failed previous fusion (pseudoarthrosis)

Summary of Technological Characteristics

The SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) instrumentations are manufactured in made in Titanium Ti-6Al-4V ELI complying with ASTM F136. The LUMIS™ Pedicle screw system is

cannulated. The devices provide correction and rigid stabilization of the spine during development of solid bone fusion following corrective spine surgery for a number of indications (listed above).

Performance data

The SpineVision® Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) conform to special control established for Pedicle Screw Spinal System and to "Spinal System 510(k)s – Guidance for Industry and FDA Staff Document" issued on May 3, 2004.

No additional testing has been performed for the added components.

No clinical data has been presented.

Substantial equivalence

SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are substantially equivalent to their predicate devices Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) in terms of intended use, indications for use, material, design, mechanical properties and function.

Conclusion

Engineering analysis and design validation/verification were used to support substantial equivalence. SpineVision Universal Lumbar Intuitive System (U.L.I.S.™ System), and Lumbar Universal Minimally Invasive System (LUMIS™ System) are as safe, as effective, and performs as safety and effectively as their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2013

SpineVision S.A.
% Ms. Helene Plas
Quality Affairs & Regulatory Affairs Manager
Antony Parc II, 10 Place du Général de Gaulle
CS 70001, Antony Cedex, 92184
FRANCE

Re: K130302
Trade/Device Name: SpineVision LUMIS™ Cannulated and U.L.I.S. ™ Polyaxial Pedicle Screw Fixation Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWQ, KWP
Dated: June 13, 2013
Received: July 1, 2013

Dear Ms. Plas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K130302

Device Name:

SpineVision LUMIS™ Cannulated Polyaxial Pedicle Screw Fixation System

SpineVision U.L.I.S.™ Polyaxial Pedicle Screw Fixation System

Indications for Use:

When used for anterior screw fixation or as a posterior, non-pedicle system of the non-cervical spine, the U.L.I.S.™ and LUMIS™ systems are indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- tumors
- failed previous fusion (pseudoarthrosis)

The U.L.I.S.™ and LUMIS™ systems are pedicle screw systems indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
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- degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- spinal tumor
- failed previous fusion (pseudoarthrosis)

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130302